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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,236	06/11/2001	Sally Freeman	39-232	4594

7590 09/25/2002

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EXAMINER

SCHMIDT, MARY M

ART UNIT PAPER NUMBER

1635

DATE MAILED: 09/25/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,236

Applicant(s)

FREEMAN ET AL.

Examiner

Mary Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 24-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 24-30, 32 and 37-45, drawn to compositions and methods including formula I and formula II compounds.

Group II, claim(s) 24-29, 31, 32 and 37-45, drawn to compositions and methods including formula I and formula III compounds.

Group III, claim(s) 24, 33-35 and 37-45, drawn to compositions and methods including formula IV and V compounds.

Group IV, claim(s) 24, 33, 34, 36 and 37-45, drawn to compositions and methods including formula IV and VI compounds.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

MPEP 1875.01 restates 37 CFR 1.475(b): "An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories...."; 37 CFR 1.475(d): "If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereof will be considered as the main invention in the claims...."

In the instant case, the claims are drawn to multiple conjugate products and methods of using said products because the claimed conjugates rely on unique structures of aromatic ring systems. Formula I and IV are distinct from each other

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because of the different placement of R1 and R2 groups (see claims 29 and 34). Formula II and Formula III as well as Formula V and Formula VI are further distinct from each other because of the different aromatic ring systems. Each of these formulas is a unique conjugate, and does not share, one with another, a common core structure, or a common property or activity, and are thus not art recognized as belonging to the same class of compounds. As such, the different conjugates do not meet the criteria for unity of invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The claims are deemed to correspond to the species listed above in the following manner:

If either of Groups I or II is selected, in claim 29: the following **linkers**: (1) O, (2), -NH, (3) S, (4) an amide, (5) alcohol, (6) phenol, (7) carboxylic acid (carboxylate), (8) carbonate, (9) phosphate, (10) sulphate, (11) sulphonate; **and** the following **R1, R2, R3, and R4** groups: hydrogen, substituted or unsubstituted alkyl (e.g. C1-4), aryl, halide, amine, alkoxy, ether, ester, alcohol, phenol, nitro, amide, thiol, sulphate, phosphate, phosphonate. Thus one linker is to be selected as well as one group for each of the R1, R2, R3 and R4 side groups.

If either of Groups III or IV is selected, in claim 34: (I) the **R1, R2 and R3** groups: hydrogen, substituted or unsubstituted alkyl (e.g. C1-4), aryl, halide, amine, alkoxy, ether, ester, alcohol, phenol, nitro, amide, thiol, sulphate, phosphate, phosphonate. Thus one member is to be selecte for each of the R1, R2 and R3 groups.

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: In Group I, claims 24-28, 30, 32, 37-45; in Group II, claims 24-28, 31, 32, 37-45; in Group III, claims 24, 33, 35, 37-45; in Group IV, claims 24, 33, 36, 37-45.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, the Markush group shall be regarded as being of similar nature when (a) all alternatives have a common property or activity and (B)(1) a common structure is present, i.e. a significant structure is shared by all of the alternatives or (b)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

In the instant case, the different side groups of the Markush-groups of claims 29 and 34 render the conjugates unique inventions since each conjugate has a different significant structure and does not share a common structure. Since the different side groups create conjugates having different functions and mechanism of action based on

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the different side group, there is not a common structure that unifies the conjugates as an art recognized class of compounds. Therefore, the guidelines of PCT Rule 13.2 are not met by the different compounds listed in the Markush groups of claims 29 and 34.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary M. Schmidt, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, Kay Pinkney, whose telephone number is (703) 305-3553.

Melissa Schmidt

September 24, 2002

A handwritten signature in black ink, appearing to read "M. Schmidt", is located at the bottom right of the page.